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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/211,483	08/24/2005	Guillermo J. Tearney	034806/US/2 -475387-00135	6904
30873	7590	02/17/2009	EXAMINER	
DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT 250 PARK AVENUE NEW YORK, NY 10177			CHAO, ELMER M	
Patent Mail Received FEB 20 2009			ART UNIT	PAPER NUMBER
			3737	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CONF

Office Action Summary	Application No.	Applicant(s)	
	11/211,483	TEARNEY ET AL.	
	Examiner	Art Unit	
	ELMER CHAO	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-68 is/are rejected.
- 7) ☒ Claim(s) 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/28/2008; 11/13/2007; 5/17/2007; 12/7/2006;</u> | 6) <input type="checkbox"/> Other: _____ |
| <u>8/24/2006; 6/15/2006; 3/17/2006; 2/21/2006; 1/17/2006; 12/13/2005; 11/4/2005;</u> | |
| <u>10/5/2005; 8/24/2005.</u> | |

DETAILED ACTION

1. Acknowledgement is made of the preliminary amendment filed 11/21/2007.

Claim Objections

2. **Claim 53** is objected to because of the following informalities: the claim recites "the second fluid", which has insufficient antecedent basis. Since several of the amendments made in the preliminary amendment involve crossing out the word "second", Examiner will assume that Applicants intended to cross out the word "second" in claim 53 as well. Appropriate correction is required.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Applicant is advised that should **claim 59** be found allowable, **claim 60** will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

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one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. **Claim 63** is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "software arrangement" is not considered statutory subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 44 and 45** recite the limitation "the quality of image metric". There is insufficient antecedent basis for this limitation in the claim.

9. **Claims 44 and 45** recite the limitation "the specific level". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. **Claims 1, 2, 4, 7, 9-12, 27-34, 36, 38, 39, 54-57, and 64-68** are rejected under 35 U.S.C. 102(b) as being anticipated by Chin et al. (U.S. 4,998,972).

Regarding **claims 1, 2, 4, 7, 9, 10, 12, 36, 38, and 39**, Chin et al. teach a method for imaging a structure, comprising: (a) delivering a portion of a volume of a fluid using a fluid delivery arrangement to an area proximal to the structure (abstract, refer to "irrigation system...flush"; and (b) after step (a), imaging at least a portion of the structure using an imaging arrangement which is associated with an article of manufacture at least one of during or after the volume of the fluid is delivered to the external location (abstract, refer to "pulsatile introduction"; col. 1, lines 63-66, refer to "flush cycle"), wherein at least one of the imaging arrangement or the article of manufacture is translated along a path which approximately corresponds to an axis of extension of a surface at least one of during or after imaging the structure (col. 6, lines 60-65, refer to "advancement rate"); and directing light to the structure (see at least fig. 1, item 14, refer to "light source"); wherein the surface is the internal surface of the blood vessel (see at least fig. 4-7).

Regarding **claim 11**, Chin et al. teach at least one optical fiber operatively connected to the directing arrangement (col. 2, lines 5-16); and an image processing arrangement operatively connected to the at least one optical fiber (fig. 3, item 10).

Regarding **claims 27-34, 54-57, and 64**, Chin et al. teach the method of claim 36, wherein step (b) further comprises obtaining data associated with the structure (col.

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1, line 66 – col. 2, line 4, the operator would obtain data inherently by watching in real time, thereby obtaining data), and further comprises: (c) controlling at least one of the fluid delivery arrangement and the imaging arrangement as a function of the data (col. 2, lines 16-42); wherein step (c) comprises controlling the translation of the imaging arrangement (the operator would have to place and move the catheter during the procedure); wherein step (c) comprises controlling the fluid delivery of the fluid delivery arrangement (see at least fig. 2, item 34); wherein step (c) comprises controlling the translation of the imaging arrangement and the fluid delivery of the fluid delivery arrangement (col. 1, line 66 - col. 2, line 4; col. 2, lines 16-42; fig. 2, item 34).

Regarding **claims 65-68**, Chin et al. teach the apparatus as described above which is at least fully capable of performing the functional limitations as recited by the claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claims 8 and 63** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al.

Regarding **claim 8**, Chin et al. teach the limitations as discussed above but fail to explicitly teach a transparent fluid reservoir. However, in just about any field that utilizes

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fluid reservoirs, such as under the hood of a car, transparent fluid reservoirs are widely utilized (see window washer fluid reservoir in a car). Therefore, it would have been obvious to a person of obvious skill in the art at the time of the invention to use a transparent fluid reservoir in order to monitor the amount of fluid remaining (for motivation check the fluid levels in a car via the transparent fluid reservoirs).

Regarding **claim 63**, Chin et al. teach the limitations as discussed above but fail to explicitly teach a software arrangement. However, providing a software arrangement to conduct all the steps as recited in claim 63 would be a method of automating an activity. Therefore, it would have been obvious to a person of obvious skill in the art at the time of the invention to use provide a software arrangement capable of performing all of the limitations as described in the claims in order to automate a manual activity (for motivation see *In re Venner*, 262, F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)).

14. **Claims 3, 23, 37 and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al. in view of Tashiro (U.S. 4,827,907). Chin et al. teach the limitations as discussed above but fail to explicitly teach the fluid being transparent to the imaging light. However, in the same field of endeavor, Tashiro teach a fluid transparent to light (col. 1, lines 20-26). Therefore, it would have been obvious to a person of obvious skill in the art at the time of the invention to use a fluid that is transparent to the imaging light in order to make an observation without hindrance (for motivation see col. 1, lines 24-26). Alternatively or additionally, medical imaging applications also utilize the same advantages of transparent reservoirs.

15. **Claims 5, 6, 40-49, 52, and 58-61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al. in view of Tashiro, further in view of Mollenauer et al. (U.S. 5,730,731).

Regarding **claims 5, 6, 40 and 41**, Chin et al. and Tashiro teach the limitations as discussed above but fail to explicitly teach a syringe and pump. However, in the same field of endeavor, Mollenauer et al. teach a syringe and pump system (col. 2, lines 21-35). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use the syringe and pump system as taught by Mollenauer et al. in order to prevent vessel overpressure and to provide instant pressure with instant flow for observation through the angioscope (for motivation see col. 2, lines 35-46).

Regarding **claims 42, 43, and 58-61**, Chin et al. do not explicitly teach obtaining a characteristic and translating the arrangement if the characteristic is outside the range. However, Mollenauer et al. do teach that in the field of angioscopy, the angioscope is moved to certain positions of interest and then viewed (col. 1, lines 22-38). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to obtain a characteristic (location of the angioscope by imaging) and continue to translate the angioscope and iteratively image as long as the location of interest is out of the intended range in order to reach the intended imaging destination (for motivation see col. 1, lines 27-31 and 33-38).

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Regarding **claims 46-49 and 52**, Chin et al. teach stopping the imaging procedure (col. 2, lines 25-28). Therefore, stopping the imaging would be obvious to one of ordinary skill in the art in order to keep a continuous image on the screen. Recommencing the imaging would be obvious in order to move on to another location in the vessel (for motivation see Mollenauer et al., col. 1, lines 27-31 and 33-38). Alternatively, Chin et al. teach recommencing imaging in order to periodically refresh and update the image (for motivation see col. 2, lines 29-32; also see col. 1, line 66 – col. 2, line 4).

Regarding **claims 44 and 45**, Chin et al. teach that the quality of image metric is below a specific level if blood is detected or if the image of the structure is at least partially blocked by blood (col. 1, lines 37-40, the quality of image metric would suffer when blood is detected in the image, hence the use of a fluid flush).

16. **Claims 13-22, 24-26, 35, 50, 51, and 62** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al. in view of Tashire, further in view of Mollenauer et al., and further in view of Tearney et al. (U.S. 6,134,003).

Regarding **claims 22, 35, 50, and 62**, Chin et al., Tashire, and Mollenauer et al. teach the limitations as discussed above but fail to explicitly teach the imaging modality being optical coherence tomography. However, in the same field of endeavor, Tearney et al. teach using rotational optical coherence tomography (abstract; col. 8, lines 50-56; also see fig. 1-19 for the rotational configurations). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use

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rotational optical coherence tomography apparatus and method as taught by Tearney et al. in order to provide the ability for 3-D imaging or intimal surface contour mapping (for motivation see col. 9, lines 1-3).

Regarding **claims 24 and 51**, Chin et al., Tashire, and Mollenauer et al. teach the limitations as discussed above but fail to explicitly teach the imaging modality being spectral domain optical coherence tomography. However, in the same field of endeavor, Tearney et al. teach using spectral domain optical coherence tomography (col. 19, lines 1-15). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use spectral domain optical coherence tomography as the imaging modality in order to provide a reflectivity profile of the structure (for motivation see col. 19, lines 12-15).

Regarding **claim 25 and 26**, Chin et al., Tashire, and Mollenauer et al. teach the limitations as discussed above but fail to explicitly teach a guide catheter. However, in the same field of endeavor, Tearney et al. teach using a guide catheter (fig. 12, item 334; col. 12, lines 51-63). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use a guide catheter in order to direct a catheter or endoscope through an artery or vein (for motivation see col. 12, lines 11-13).

Regarding **claims 13-21**, Chin et al., Tashire, Mollenauer and Tearney et al. teach the apparatus and method as described above. Tearney et al. also teach the apparatus which is fully capable of performing the functional limitations recited by the claims.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELMER CHAO whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

/E. C./
Examiner, Art Unit 3737
2/4/2009

Notice of References Cited	Application/Control No. 11/211,483	Applicant(s)/Patent Under Reexamination TEARNEY ET AL.	
	Examiner ELMER CHAO	Art Unit 3737	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,827,907 A	05-1989	Tashiro, Yoshio	600/109
*	B	US-4,998,972 A	03-1991	Chin et al.	600/109
*	C	US-5,730,731 A	03-1998	Mollenauer et al.	604/246
*	D	US-6,134,003 A	10-2000	Tearney et al. ✓	356/479
	E	US-			
	F	US-			
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	K	US-			
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